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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/020,531	12/14/2001	Sukhendu B. Dev	GENE1180-2	1163

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EXAMINER

LAM, ANN Y

ART UNIT PAPER NUMBER

1641

DATE MAILED: 09/08/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/020,531

Applicant(s)

DEV ET AL.

Examiner

Ann Y. Lam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,7-14,16-21 and 23-34 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

- 5) ☐ Claim(s) _____ is/are allowed.

- 6) ☒ Claim(s) 1-5,7-14,16-21 and 23-34 is/are rejected.

- 7) ☐ Claim(s) _____ is/are objected to.

- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 7-14 and 16-21 and 23-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Leone et al., 5,505,700.

Leone et al. discloses a catheter (11) having at least one inflatable balloon portion (16 and 17); at least one infusion opening (19) for introducing the composition into a vessel; a first electrode (35) on the catheter positioned adjacent to at least one infusion opening ; and a second electrode (36) on the catheter positioned proximal to but spaced from the first electrode a distance that allows an electric field to be generated when a voltage is applied between the first and second electrodes after the catheter has been inserted into the vessel, wherein the electric field is sufficient in strength to electroporate cells in the vessel, see column 4, lines 49-63, and column 7, lines 41-44.

With respect to claims 2, 11, 18, an electrical source is connected to the first and second electrodes for applying a voltage between the electrodes, see column 4, line 61.

With respect to Claims 3, 12 and 19, the vessel is a blood vessel (22).

As to claims 4, 13 and 20, the first electrode (35) is formed at least in part by a biologically inert material, see column 4, lines 56-57.

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As to claims 5, 14 and 21, the second electrode is a guidewire in the catheter, see column 4, line 63.

As to claim 7, the catheter has two inflatable balloon portions (16 and 17).

As to claim 8, the at least one infusion opening (19) is between the two inflatable balloon portions (16 and 17), see Figure 2.

As to claim 9, the first electrode (35) is coincident with the at least one infusion opening (19).

As to claims 10 and 17, Leone et al. discloses a first inflatable balloon portion (17) near a distal end of the catheter; a second inflatable balloon portion (16) proximal the first inflatable balloon, wherein inflation of the first and second balloon occludes a vessel (22) between the first and second balloon; an infusion opening (19) for introducing a composition wherein the infusion opening is located between the first and second balloon portions; a first electrode (35) positioned adjacent to or integral with the infusion opening; and a second electrode (36) on the catheter positioned proximal to but spaced from the first electrode a distance that allows an electric field to be generated when a voltage is applied between the first and second electrodes after the catheter has been inserted into the vessel, wherein the electric field is sufficient in strength to electroporate cells in the vessel, see column 4, lines 49-63, and column 7, lines 41-44.

As to claim 16, the at least one inflatable balloon (16 or 17) is near the distal end of the catheter.

As to claim 18, an electrical source (15) is connected to the first and second electrodes for applying a voltage between the electrodes in an amount sufficient to cause electroporation of at least one cell.

As to claim 23, 25 and 27, the first and second electrode is separately selected to be a single electrode or multiple electrodes, see column 4, lines 57-59.

As to claims 24, 26 and 28, the multiple electrodes are interdigitated electrodes or concentric ring electrodes, see column 4, lines 63-67.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 29-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leone et al., 5,505,700.

Leone et al. teach the invention substantially as claimed, see above. However, Leone et al. does not specifically disclose that the first and second electrodes are suitable to receive an electric pulse having an electroporating voltage in the range as claimed, or wherein the electric field strength is in the range as claimed.

Leone et al. however does teach that the invention can be used for iontophoresis or electroporation, see column 7, lines 39-44, and thus it would have been obvious to vary the Leone et al. device such that the device is capable of receiving an electric

pulse having an electroporating voltage or electric field strength as specifically claimed, as necessary for achieving iontophoresis or electroporation.

Response to Arguments

Applicant's arguments filed July 9, 2003 have been fully considered but they are not persuasive.

Applicant argues that Leone et al.'s definition of electroporation is the electrical breakdown of cells which contain substances such as hemolytic compounds, genes, and the like, see top of page 10 of Applicant's response. Applicant further argues that, in contrast, Applicant's specification describes electroporation as a process that does not appreciably harm healthy cells but rather creates pores in cells without permanently damaging them, see page 10.

In response, Examiner asserts that Leone et al.'s definition of electroporation, i.e., the electrical breakdown of cells, does not necessarily mean that the cells are permanently damaged or harmed. In any case, the Leone et al. device is capable of electroporation since the voltage can be varied (for iontophoresis or for electroporation) see column 5, lines 23-26, and column 6, lines 62-65, and column 7, lines 41-44.

Applicant further argues that applicant teaches use of Applicant's device to deliver therapeutic agents into cells rather than breaking down the cells to release substances already in the cells. In response, Examiner emphasizes that Applicant is claiming a device. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to

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patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). In other words, whether the Leone et al. device is used to create pores in cells or to release materials in cells, the device itself is capable of electroporation. Moreover, the device is capable of electroporation without permanently damaging the cells, since the voltage can be varied (for iontophoresis or for electroporation) see column 5, lines 23-26, and column 6, lines 62-65, and column 7, lines 41-44.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Abela, 5,246,437, teaches electroporation (i.e., creating pores in vivo) and discloses that it is known in the art to use two inflated balloons to create a temporary chamber which allows the exposure of the arterial wall to an agent, see column 1, lines 43-46. Brown, III et al., 6,219,577, teaches a device capable of both iontophoresis and electroporation (i.e., creation of transient pores in cell surface membranes) (see column 3, lines 38-53) and teaches that double balloon catheters have been used to confine a drug solution to a specific segment of a blood vessel, see column 2, lines 8-11.

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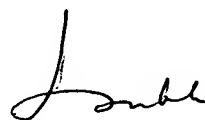
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is (703) 306-5560. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703)305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-4242 for regular communications and (703)308-4426 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.

A.L.

September 7, 2003



LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

09/07/03